

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD.,

Plaintiffs,

v.

ACTAVIS, INC., and ACTAVIS
ELIZABETH LLC,

Defendants.

REDACTED PUBLIC VERSION
ISSUED 3/27/17

C.A. No. 14-1487-LPS

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD.,

Plaintiffs,

v.

EZRA VENTURES, LLC,

Defendant.

C.A. No. 15-150-LPS

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD.,

Plaintiffs,

v.

HEC PHARM CO., LTD., HEC PHARM
GROUP, and HEC PHARM USA INC.,

Defendants.

C.A. No. 15-151-LPS

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI SUGAR CO.,
LTD.,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

C.A. No. 15-975-LPS

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MEMORANDUM OPINION

March 17, 2017
Wilmington, Delaware


STARK, U.S. District Judge:

I. INTRODUCTION

These are patent infringement actions brought by Novartis AG (“NAG”), Novartis Pharmaceuticals Corporation (“NPC”), Mitsubishi Tanabe Pharma Corporation (“Mitsubishi”), and Mitsui Sugar Co., Ltd. (“Mitsui”) under the Hatch-Waxman Act. Plaintiffs separately filed suit against Defendants Actavis, Inc. and Actavis Elizabeth LLC; Ezra Ventures, LLC; HEC Pharm Co., Ltd., HEC Pharm Group, and HEC Pharm USA Inc.; and Apotex Inc., and Apotex Corp. Each defendant submitted an Abbreviated New Drug Application to market a generic version of Gilenya, a drug containing the active ingredient fingolimod. (*E.g.*, C.A. No. 14-1487 D.I. 1 at ¶ 1)¹ Plaintiffs assert Orange Book-listed U.S. Patent No. 5,604,229. Mitsubishi and Mitsui own the ’229 patent, and NPC holds the New Drug Application for Gilenya. (*Id.* at ¶¶ 22-23) The ’229 patent describes and claims 2-amino-1,3-propanediol compounds, including fingolimod, which show immunosuppressive action. (’229 patent, col. 1, ll. 8-10)

Pending before the Court are Defendants’ renewed motion to dismiss NPC and NAG for lack of standing (D.I. 151), Plaintiffs’ cross-motion for partial summary judgment on Novartis’s standing (D.I. 159), and Plaintiffs’ motion for leave to file a surreply (D.I. 172). The Court heard argument on the pending motions on November 10, 2016. (D.I. 196 (“Tr.”)) A bench trial is scheduled to begin on April 24, 2017.

For the reasons stated below, the Court will grant in part and deny in part Defendants’ motion to dismiss, grant in part and deny in part Plaintiffs’ cross-motion for summary judgment on standing, and grant Plaintiffs’ motion for leave to file a surreply.

¹Unless otherwise noted, all citations to the docket are to C.A. No. 14-1487.

II. BACKGROUND

In 1994, the inventors of the '229 patent assigned their rights to Yoshitomi Pharmaceutical Industries, Ltd. ("Yoshitomi"), a pharmaceutical company, and Taito Co., Ltd. ("Taito"), a sugar company. (D.I. 153 Ex. A at 1) For purposes of the pending motions, Defendants do not contest that Yoshitomi became Mitsubishi and Taito became Mitsui, or that Mitsubishi and Mitsui are co-owners of the '229 patent. (D.I. 152 at 3)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In 1997, Yoshitomi selected Novartis Pharma AG ("NPAG") as its licensee. On June 17, 1997, Taito entered into an agreement with Yoshitomi with respect to Yoshitomi's licensing efforts for fingolimod. (D.I. 153 Ex. C) ("1997 Taito Statement") [REDACTED]

[REDACTED]

III. LEGAL STANDARDS

“Standing is a constitutional requirement pursuant to Article III and it is a threshold jurisdictional issue.” *Abraxis Bioscience, Inc. v. Navinta LLC*, 625 F.3d 1359, 1363 (Fed. Cir. 2010) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). The plaintiff bears the burden of persuasion to show it has standing. *See Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991); *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005). “Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of jurisdiction over the subject matter, or if the plaintiff lacks standing to bring his claim.” *Samsung Elecs. Co., Ltd. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008).

“A challenge to subject matter jurisdiction under Rule 12(b)(1) may be either a facial or a factual attack.” *Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). “The former challenges subject matter jurisdiction without disputing the facts alleged in the complaint” *Id.* However, where subject matter jurisdiction is challenged based upon the sufficiency of jurisdictional facts, the Court is “free to weigh the evidence and satisfy itself as to the existence of its power to hear the case.” *Mortensen v. First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 891 (3d Cir. 1977). When considering a factual challenge to standing, “no presumptive truthfulness attaches to plaintiff’s allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.” *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n.3 (3d Cir. 2006).

Standing “is comprised of both constitutional and prudential components.” *Oxford Assocs. v. Waste Sys. Auth. of E. Montgomery Cty.*, 271 F.3d 140, 145 (3d Cir. 2001). The requirement of constitutional standing derives from the Article III “case” or “controversy” requirement, compelling “a plaintiff to demonstrate that he or she suffered ‘injury in fact,’ that the injury is ‘fairly traceable’ to the actions of the defendant, and that the injury will likely be redressed by a favorable decision.” *Id.* “[T]he touchstone of constitutional standing in a patent infringement suit is whether a party can establish that it has an exclusionary right in a patent that, if violated by another, would cause the party holding the exclusionary right to suffer legal injury.” *WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010). Prudential standing requires, among other things, that “a litigant assert his or her own legal rights and not rely on the rights or interests of third parties.” *Hill ex rel. Hill v. Pa. Dep’t of Corr.*, 521 Fed. App’x 39, 40 (3d Cir. 2013) (citing *Warth v. Seldin*, 422 U.S. 490, 499 (1975)).

A patent is “a bundle of rights which may be divided and assigned, or retained in whole or part.” *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 875 (Fed. Cir. 1991); *see also* 35 U.S.C. § 261 (“[P]atents, or any interest therein, shall be assignable in law by an instrument in writing.”). While all such rights are initially held by the named inventor, they may be licensed or assigned to multiple parties, and “[w]hen a sufficiently large portion of this bundle of rights is held by one individual, we refer to that individual as the owner of the patent, and that individual is permitted to sue for infringement in his own name.” *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1360 (Fed. Cir. 2010). Accordingly, plaintiffs who “hold all legal rights to the patent as the patentee or assignee of all patent rights” can sue in their own name alone. *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1339-40 (Fed. Cir.

2007) (“Unquestionably, a patentee who holds all the exclusionary rights and suffers constitutional injury in fact from infringement is one entitled to sue for infringement in its own name.”).

Additionally, if a patentee transfers “all substantial rights” in the patent to an assignee, “this amounts to an assignment or a transfer of title, which confers constitutional standing on the assignee to sue for infringement in its own name alone.” *Id.* at 1340; *see also Sicom*, 427 F.3d at 976; *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1377 (Fed. Cir. 2000) (“[W]here the patentee makes an assignment of all substantial rights under the patent, the assignee may be deemed the effective ‘patentee’ under 35 U.S.C. § 281 and thus may have standing to maintain an infringement suit in its own name.”).

Finally, exclusive licensees – those parties who “hold exclusionary rights and interests created by the patent statutes, but not all substantial rights to the patent” – have constitutional standing. *Morrow*, 499 F.3d at 1340. “However, these exclusionary rights ‘must be enforced through or in the name of the owner of the patent,’ and the patentee who transferred these exclusionary interests is usually joined to satisfy prudential standing concerns.” *Id.* at 1340; *see also Propat Int’l Corp. v. Rpost, Inc.*, 473 F.3d 1187, 1193 (Fed. Cir. 2007). Put another way, “unlike an assignee that may sue in its own name, an exclusive licensee having fewer than all substantial patent rights . . . that seeks to enforce its rights in a patent generally must sue jointly with the patent owner.” *Intellectual Prop. Dev., Inc. v. TCI Cablevision of CA, Inc.*, 248 F.3d 1333, 1347-48 (Fed. Cir. 2001). “The patentee is joined for the purpose of avoiding the potential for multiple litigations and multiple liabilities and recoveries against the same alleged infringer.” *Morrow*, 499 F.3d at 1340; *see also Int’l Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273,

1278 (Fed. Cir. 2007).

“By contrast, a bare licensee, i.e., a party with only a covenant from the patentee that it will not be sued for infringing the patent rights, lacks standing to sue third parties for infringement of the patent.” *Propat*, 473 F.3d at 1193. “[A]n infringement action brought by a bare licensee must be dismissed. A bare licensee cannot cure its lack of standing by joining the patentee as a party.” *Id.* at 1193-94.

IV. DISCUSSION

A. Plaintiffs’ Motion for Leave to File Surreply

Local Rule 7.1.2 provides that parties may submit additional papers after briefing is complete only with the Court’s approval. The Court may grant leave to file a surreply if it responds to new evidence, facts, or arguments. *See St. Clair Intellectual Prop. Consultants, Inc. v. Samsung Elecs. Co.*, 291 F.R.D. 75, 80 (D. Del. 2013). Plaintiffs seek leave to file a surreply to respond to Defendants’ argument, raised in their combined reply brief in support of Defendants’ renewed motion to dismiss and answering brief in opposition to Plaintiffs’ cross-motion for partial summary judgment (D.I. 168), that NPAG is free to license to non-Novartis entities. As the proposed surreply (D.I. 172 Ex. A) is identical to Plaintiffs’ reply brief in support of their cross-motion for partial summary judgment (D.I. 173), the Court will grant Plaintiffs’ request for leave and deem the surreply filed.

B. NPAG Has Exclusive Rights in the ’229 Patent

It is uncontested that Mitsubishi and Mitsui are the owners of the ’229 patent and are named plaintiffs in this case. (D.I. 152 at 3) Therefore, the relevant inquiry for standing purposes is whether the Novartis plaintiffs have an exclusive license to the ’229 patent. The

Court will begin with NPAG, the entity that entered into a license agreement with Yoshitomi.

It is undisputed that Japanese law governs the license agreement between Yoshitomi and NPAG. It is also undisputed that under Japanese law, “a contract between parties is formed by manifestation of intention by way of offer and acceptance.” (D.I. 161 Ex. 4 at ¶ 3.4)³ “[M]anifestation of intention (including for license agreements) need not be made in writing: it can be made orally or in any manner.” (*Id.*) Additionally, “Japanese courts [] consider all relevant evidence in attempting to determine the true intention of the parties.” (D.I. 161 Ex. 27 at 14) Further, Japanese law recognizes third-party beneficiary contracts and agency principles. (D.I. 161 Ex. 4 at ¶¶ 3.7, 3.8)

Defendants focus on the 1997 Taito Statement, executed by Taito and Yoshitomi several months before the Yoshitomi executed its license agreement with NPAG, to argue that NPAG does not have exclusionary rights in the ’229 patent. (*See* D.I. 153 Ex. C) In particular, Defendants argue that the type of exclusive license Taito authorized Yoshitomi to grant to NPAG retained for Taito the right to sue for an injunction.

Japanese law recognizes two types of exclusive licenses in Japan: “dokusenteki jishshiken” and “senyo jishshiken.” (D.I. 161 Ex. 6 at ¶ 24) According to Defendants, under a “dokusenteki jishshiken” license, “the patentee retains all rights not expressly granted.” (*Id.*) Accordingly, the terms of a license agreement that is described by the term “dokusenteki jishshiken” “will vary with the intentions and negotiations of the parties.” (D.I. 161 Ex. 20 at 70:12-17)

³The record includes three declarations from the parties’ Japanese law experts, as well as these experts’ deposition testimony. (*See* D.I. 161 Ex. 4-6, 20-21; *see generally* Fed. R. Civ. P. 44.1 (“In determining foreign law, the court may consider any relevant material or source, including testimony, whether or not submitted by a party or admissible under the Federal Rules of Evidence.”))

[REDACTED]

[REDACTED] Defendants assert [REDACTED]

[REDACTED]

[REDACTED] Taito did not consent to Yoshitomi granting to NPAG the right to sue for an injunction.

Plaintiffs counter that Taito gave Yoshitomi plenary authority to license the '229 patent. Plaintiffs identify a number of documents that evince Taito's consent to be bound by the agreement Yoshitomi entered into with NPAG. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Therefore, even before Yoshitomi engaged in any licensing arrangement with Novartis, Taito agreed that Yoshitomi would have considerable control when selecting an overseas licensee.

Then, around the same time Yoshitomi was going to execute its license agreement with Novartis, Taito and Yoshitomi agreed to the June 1997 Taito Statement, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This evidence demonstrates that Taito consented to Yoshitomi conducting license negotiations and Taito intended to be bound by those negotiations. [REDACTED]

[REDACTED]

[REDACTED]

Additionally, in 2009, Taito's successor, Mitsui, ratified the NPAG license agreement,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The 2009 agreement, therefore, is strong evidence that the patent owners intended to grant – and understood that they had granted – NPAG the right to sue for an injunction.

Therefore, the Court is persuaded that Taito gave Yoshitomi authority to license its rights in the '229 patent, and Yoshitomi did so, including by granting NPAG the right to: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Based on all of the evidence summarized above, the Court concludes that the patent owners granted NPAG the right to sue for an injunction.

Additionally, both patent owners at the time of the licensing agreement, Yoshitomi and Taito, agreed not to license the '229 to any party other than Novartis and its sublicensees. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Therefore, NPAG received a promise of exclusivity under the patent: the patent owners promised not to license the patent to a party seeking to practice the '229 patent with respect to fingolimod products for use in transplantation and autoimmune disease in the United States. Such promise is further evidence of an exclusive license. *See WiAV*, 631 F.3d at 1267; *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995).

Defendants argue that NPAG is not an exclusive licensee because the patent owners

retained certain rights. [REDACTED]

[REDACTED]

[REDACTED] That the patent owners have reserved for themselves rights in the licensed patent does not preclude the license from being exclusive. *See Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1347-49 (Fed. Cir. 2016). Consistent with this conclusion is the reality that the rights retained by the patent owners do not, here, include the right to authorize Defendants to engage in the behavior in which Defendants wish to engage. (Tr. at 50) That is, the patent owners cannot retain Defendants as contract manufacturers, for example, and thereby insulate Defendants from liability for the allegedly infringing activities that give rise this suit.

Finally, Defendants argue that NPAG does not have exclusionary rights in the '229 patent because the patent is not commensurate in scope with the license. The patent claims many 2-amino-1,3-propanediol compounds and is not limited to any field of use, [REDACTED]

[REDACTED]

[REDACTED] ([REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

As already noted, a patent is “a bundle of rights which may be divided and assigned, or retained in whole or part.” *Vaupel*, 944 F.2d at 875. Here, NPAG secured rights to just some

sticks in that bundle. “Because an exclusive licensee derives its standing from the exclusionary rights it holds, it follows that its standing will ordinarily be coterminous with those rights.”

WIAV, 631 F.3d at 1266. Plaintiffs’ assertion of infringement of the ’229 patent here is coterminous with the rights that NPAG holds: exclusive rights to fingolimod for treatment of autoimmune disease in the United States. That Novartis does not have other rights to the ’229 patent does not undermine the conclusion that it has standing to bring the suit it has brought. *See id.*

Thus, NPAG has exclusionary rights, such that it can properly bring a suit for patent infringement with the patent owners, Mitsubishi and Mitsui. The license agreement gives NPAG the right to enforce the patent; the patent owners agreed not to license to non-Novartis entities; and the patent owners do not retain rights that detract from NPAG’s exclusionary rights.

NPAG, however, is not a party in these actions. Rather, other Novartis entities – NAG and NPC – are Plaintiffs. Therefore, the Court must next address Plaintiffs’ contention that NAG and NPC received exclusive sublicenses from NPAG.

C. NAG and NPC

“[I]n determining patent and license rights in complex transfers, the standard is whether the evidence as a whole convinces the trier of fact of mutual intent to transfer and vest exclusive rights.” *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, 748 F.3d 1354, 1364 (Fed. Cir. 2014). “[A]n exclusive license need not be in writing for the exclusive licensee to have standing to sue with the patentee as a co-plaintiff.” *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 288 F. App’x 697, 705 (Fed. Cir. 2008). Exclusivity may be “expressly or impliedly” created. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1025 (Fed. Cir.

2006).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Plaintiffs argue that, therefore, NAG and NPC have implied exclusive licenses.⁴

Peter Waibel, the head of US Patent Litigation for NPC, testified that the Novartis entities organized the license such that only NPAG manufactures Gilenya, only NPC markets and sells in the United States, and NAG retains the right to transfer and allocate rights among affiliates, [REDACTED]

[REDACTED]

[REDACTED] Plaintiffs also identify a service-level agreement between NPAG and NAG to further bolster their argument that NAG has exclusive rights in the '229 patent. [REDACTED]

[REDACTED]

[REDACTED] Plaintiffs assert that [REDACTED]

[REDACTED] NAG "has final say on this lawsuit and on allocating the rights NPAG licensed within the Novartis family." (D.I. 173 at 4)

⁴Defendants refer the Court to *Novartis Pharm. Corp. v. Teva Pharm. USA*, C.A. No. 05-1887 (D.N.J.), in which Novartis entities were dismissed for lack of standing on the basis that they failed to prove they were exclusive licensees. (See D.I. 153 Ex. W at 91-92) The same outcome is not warranted here. This case concerns patents, products, and licenses unrelated to those previously at issue; and Plaintiffs present evidence to show exclusivity, such as PTO filings, that is different from the evidence considered in the other case. (See D.I. 174 Ex. 41)

summary judgment with respect to NAG.⁶

The calculus is different with respect to NPC's standing, as Plaintiffs provide two key pieces of evidence that support their contention that NPAG promised exclusivity to NPC. Most importantly, NPC represented to the United States Patent and Trademark Office ("PTO") – in an application for term extension of the '229 patent – "that it [NPC] is the exclusive licensee of rights" in the patent. (D.I. 174 Ex. 41) Additionally, NPC alone owns the NDA for Gilenya. (D.I. 161 Ex. 3 at ¶ 13)

Ms. DeBenedictis, the lawyer responsible for the PTO filing, testified that she specifically looked into whether NPC had an exclusive license and, after speaking with several people, including someone at NPAG, came to the conclusion that it did. (D.I. 174 Ex. 42 at 31:21-33:9) Hence, the PTO filing, which represented NPC as the exclusive licensee, resulted from diligence of a lawyer to confirm the nature of the license, and notably, that lawyer owed a duty of candor and good faith toward the PTO in the patent term extension proceedings. *See* 37 C.F.R. § 1.765. Therefore, this filing is strong circumstantial evidence that NPAG did intend to grant an exclusive license to NPC. NPC's sole ownership of the NDA for Gilenya is also consistent with having an exclusive license. *See Sanofi-Aventis*, 748 F.3d at 1364 (affirming district court's finding "that Abbott Laboratories and ALI had exclusive rights to the patented product in the

⁶Plaintiffs argue that patent standing is not properly resolved under Rule 12(b)(1). (D.I. 160 at 19-20, citing *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377 (2014); *Morrison v. Nat'l Australian Bank Ltd.*, 561 U.S. 247 (2010); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83 (1998)) Even accepting Plaintiffs' argument, the Court could convert Defendants' motion to dismiss into a motion for summary judgment and reach the same conclusion it has reached here, without the need for any additional discovery. *See Albright v. Keystone Rural Health Ctr.*, 320 F. Supp. 2d 286, 288 (M.D. Pa. 2004); *Avedis v. Herman*, 25 F. Supp. 2d 256, 262-63 (S.D.N.Y. 1998).

United States, based on Abbott Laboratories' ownership of the NDA and the relationships and agreements among the Plaintiffs").

Plaintiffs have persuaded the Court that NPC has an implied exclusive license from NPAG, and, therefore, is properly a plaintiff in this case. Accordingly, the Court will deny Defendants' motion to dismiss NPC and grant Plaintiffs' motion for summary judgment with respect to NPC.⁷

V. CONCLUSION

For the foregoing reasons, the Court will dismiss NAG as a plaintiff but not dismiss NPC. Accordingly, the Court will grant in part and deny in part Defendants' motion to dismiss and Plaintiffs' cross-motion for partial summary judgment on standing. The Court will also grant Plaintiffs' motion for leave to file a sur-reply brief. An appropriate Order follows.

⁷Defendants appear to accept that if the Court denies their motion to dismiss an entity, then summary judgment as to that entity's standing is appropriate. (*See* D.I. 168)